What is a medical device?

Medical devices range from simple heating blankets, electrical hospital beds or wheelchairs to complex programmable electronic equipment such as Magnetic Resonance Imaging (MRI), medical lasers, incubators, cardiac monitors or other life-support devices.

All medical devices need to meet a rather complicated set of safety requirements. Compliance regulations heavily affect their design and manufacture, including mechanical, electrical, and software matters.

Why Standards?

Standards, regulations and verification are closely interlinked. Standardized technologies that are tested and verified for safety, quality and performance contribute to overall risk management. They also help improve processes and the understanding of device interactions.
What is a Standard?
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An IEC International Standard is an agreed and repeatable way of accomplishing the same outcome time after time and forms the basis for judging the quality and reliability of a medical device. It is a document that presents the combined expertise and know-how of many experts from all around the world and is designed to provide technical specifications or other precise criteria as technical guidance for manufacturers, testing laboratories, installers or regulators to name but a few.

From A to Z
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In the IEC, Technical Committee (TC) 62 prepares the majority of International Standards for medical devices. It focusses on safety, performance and other aspects, such as radiation protection. Together with its different subcommittees (SCs), IEC TC 62 covers a vast field of product categories including for example diagnostic imaging, radiotherapy, nuclear medicine, radiation dosimetry, electromedicine, anaesthesia, critical care, surgery, artificial respiration or paediatrics.

These International Standards provide essential guidance for medical electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

Broad cooperation
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When appropriate, and to ensure that International Healthcare Standards fit seamlessly together, IEC TC 62 and its SCs cooperate with other Committees of the IEC, ISO or other organisations, based on the expertise each organization embodies.

IEC 60601 Standard series
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The most important publication of IEC TC 62 is the IEC 60601 Standards series, which is widely accepted for basic safety and essential performance of medical electrical equipment. Compliance with this Standard series is a requirement for certification in many countries.

Medical Electrical Equipment (Reference IEC 60601-1, 3.63) is defined as: “electrical equipment having an applied part or transferring energy to or from the patient or detecting such energy to or from the patient.” That includes EEG monitors, IV pumps, imaging systems, X-ray and MRI systems, radiation therapy equipment, ECG devices, vital signs monitors, and similar devices that connect directly to a patient.

All medical devices need to meet a rather complicated set of safety requirements
Safety and performance

The IEC 60601 Standard series addresses basic safety, as well as electrical and mechanical safety; essential performance; operator protection; radiation, temperature and other hazards; programmable systems; transformers; batteries; mobile equipment; and so forth. The series contains close to 60 special requirements documents geared to specific devices.

In addition to safety design requirements, strict manufacturing rules are associated with the traceability of source materials and manufacturing procedures, as well as quality control.

Risk management

Risk management is an intrinsic part of the philosophy of the IEC in general and the IEC 60601 Standard series in particular. In a unique approach, IEC 60601-1 integrates mandatory risk management principles of ISO 14971 but applies them to device instead of process certification.

IEC 60601-1 facilitates compliance with legal and regulatory requirements specific to the healthcare area. It guides manufacturers in the identification of all hazards associated with a medical device, including for all operation modes and all fault scenarios. One outcome is a risk matrix that is associated with the use of an individual device. Probability of occurrence and severity of potential harm is documented, and all significant risks must have been addressed.

Shock protection

IEC 60601-1 also provides well-defined rules for isolation of both the patient and the operator of the device. This includes tight controls on leakage currents, voltages applied, and energy limits that can make it to the patient. Clear guidance is provided on how to design, manufacture or test external power supplies or power converters.

This is complemented by other IEC International Standards which help verify for example device stability when the power supply is briefly pulled out of the wall or during voltage fluctuations.

The IEC 60601 series of 60 Standards addresses basic safety and essential performance.
Preventing the risk of errors

Several IEC International Standards address multiple types of outside interferences that can impact the ability of a medical device to function properly. Among other things, they provide guidance for tests that evaluate the device’s ability to work correctly when faced with electromagnetic interference, radio frequency pulses, power frequency magnetic fields, etc.

They help manage risk by identifying types of error messages, system resets, component failures, changes to programmable parameters, changes of operating modes, false alarms, faulty patient information, etc. The aim is to ensure not only damage-free test survival of the medical device, but proper functioning of equipment beyond.

With the help of IEC International Standards, medical electrical equipment manufacturers are able to ensure that medical devices as well as complex systems and assemblies meet expectations for safety and effectiveness.

Supporting safety and efficiency

Several other IEC TCs and SCs also prepare International Standards that concern medical devices. For example IEC TC 29 develops Standards related to hearing aids and hearing instruments; IEC TC 87 covers the breadth of ultrasonic equipment for all diagnostic or therapeutic purposes; IEC TC 66 prepares International Standards that cover the safety requirements of electrical equipment that is used for measurement, control and laboratory use, including equipment falling under medical device regulations.

Several other IEC TCs and SCs also prepare International Standards that concern medical devices.
Testing and certification

Testing and certification of medical devices

In addition to standardization, the IEC also offers a unique globally standardized approach to testing and certification of medical devices under IECEE (IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components). Since 1986, IECEE Members certify that medical devices comply with IEC International Standards.

IECEE verifies that medical electrical and electronic devices and equipment are reliable and meet expectations in terms of performance, safety, reliability and other criteria. The System applies not only to the medical electrical equipment itself but also covers risks to patients, those who operate the equipment – doctors, nurses and technicians, for instance – and maintenance personnel.

IECEE certification is based on the principle of reciprocal acceptance. This approach is essential in facilitating international trade and allowing direct access to the marketplace for vendors, retailers or buyers. It eliminates unnecessary duplicate testing and reduces the costs related to the certification process. IECEE is also an important partner for regulators in the verification of compliance. More information on IECEE is available at www.iecee.org.

Harmonized regulation for global trade in medical devices

Today, electronics and electrical, including medical devices, are more similar than ever before. Their parts and subassemblies transit through many countries before a device is built somewhere, shipped, installed and then used – anywhere in the world. Electrical devices are generally no longer the industrial manufacture of a single country; more often than not, they are “made in the world”.

An International Standard and a global Conformity Assessment System is at its most effective when regulatory requirements come together. The ultimate aim is to achieve an outcome where one Standard, one test is accepted everywhere. That is when it offers the biggest advantages for regulators, industry and the patient.

An International Standard and a global Conformity Assessment System is at its most effective when regulatory requirements are harmonized.
Broader access to affordable quality healthcare

Broad use of harmonized, globally agreed technical rules — generally IEC International Standards — helps increase the availability of safe, affordable, quality medical devices. At the global level this results in broader access to better healthcare.

While the trade of medical electrical equipment is global, the regulatory environment is still local to each specific jurisdiction. This lends emphasis and importance to an international approach to standardization but also to greater regulatory convergence.

Clear, harmonized regulatory guidelines help encourage investment in R&D and future innovations and reassure manufacturers that regulatory requirements will remain sensible.

However, when regulation is too severe in terms of safety or ambiguous or confusing in its requirements, it can hinder investment and with it patient access to affordable diagnosis and treatment options.

Use of International Standards with little or no national/regional variations is a guarantee for optimum patient access to reasonably priced and safe healthcare.

Clear, harmonized regulatory guidelines help encourage investment in R&D and future innovations.
International Standards

How are IEC International Standards developed?

IEC International Standards are voluntary and consensus-driven. Many experts from many different countries participate in the standardization process on the global, neutral and independent IEC platform. That is where they try to achieve consensus on solutions to challenges that are faced by multiple countries.

Only when at least a 2/3 majority of all experts have reached agreement; all major issues have been addressed and major opposition has been overcome, can a Standard be sent for approval by the IEC Members.

Each Member country can invite all national stakeholders to comment on the proposed Standard. Public commenting via the IEC website allows further experts to share their know-how and insights: www.iec.ch/comment

This national input is then brought to the global level in the IEC. At that point every Member country can comment, accept or reject the proposed Standard. In this representative process every country has one vote. This helps “level the playing field”; no single country dominates the others and this results in an International Standard that is universally relevant.

IEC International Standards offer a double consensus at the expert and at the country levels: they combine the know-how and consensus of thousands of technical experts, as well as the vote and approval of many countries.
The IEC, headquartered in Geneva, Switzerland, is the world’s leading publisher of International Standards for electrical and electronic technologies. It is a global, independent, not-for-profit, membership organization (funded by membership fees and sales). The IEC includes 170 countries that represent 99% of world population and energy generation.

The IEC provides a worldwide, neutral and independent platform where 20 000 experts from the private and public sectors cooperate to develop state-of-the-art, globally relevant IEC International Standards. These form the basis for testing and certification, and support economic development, protecting people and the environment.

IEC work impacts around 20% of global trade (in value) and looks at aspects such as safety, interoperability, performance and other essential requirements for a vast range of technology areas, including energy, manufacturing, transportation, healthcare, homes, buildings or cities.

The IEC administers four Conformity Assessment Systems and provides a standardized approach to the testing and certification of components, products, systems, as well as the competence of persons.

IEC work is essential for safety, quality and risk management. It helps make cities smarter, supports universal energy access and improves energy efficiency of devices and systems. It allows industry to consistently build better products, helps governments ensure long-term viability of infrastructure investments and reassures investors and insurers.

Key figures

| 170 | Members and Affiliates |
| >200 | Technical committees and subcommittees |
| 20 000 | Experts from industry, test and research labs, government, academia and consumer groups |
| 10 000 | International Standards in catalogue |
| 4 | Global Conformity Assessment Systems |
| >1 million | Conformity Assessment certificates issued |
| >100 | Years of expertise |
Further information

Please visit the IEC website at www.iec.ch for further information. In the “About the IEC” section, you can contact your local IEC National Committee directly. Alternatively, please contact the IEC Central Office in Geneva, Switzerland or the nearest IEC Regional Centre.

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